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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,135	10/15/2003	Ivan Osorio	011738.00133	8261

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EXAMINER	
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ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,135	OSORIO ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/06, 2/26/06, 4/14/09 & 6/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 14, 2009 have been fully considered but they are not persuasive.

The Applicant argues that Mann (US Patent Publication 20010034542 A1) does not discloses a "range of safety". Furthermore, the Applicant states that "they are unaware of any support for the Examiner's proposition that the range between a minimum perception level and a maximum tolerable level is the same as a range of safety". However, the examiner stated in the Office Action on page 10, "the Applicant describes on page 14, paragraph 125, "the treatment therapy configuration is within a configuration range of safety. Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient". Therefore, since the stimulation is in a range of a minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, the examiner considers the stimulation to be within a range of safety".

Therefore, as previous indicated since the Applicant discloses "Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient". Thus, since a maximum tolerable level is *expected* not to diminish the health of the patient, a maximum tolerable level does meet the requirements as set forth by the Applicant to be safe. Furthermore, a range between the minimum perceived level and the maximum tolerable level would thus, in accordance with the Applicants definition of safe, constitute a range of safety. Additionally, it can be assumed that

tolerable stimulation does not diminish the health of the patient since tolerable is considered to be acceptable with few side effects or risks.

Additionally the applicant argues that the examiner has not indicated in Mann where "if the first treatment therapy is safe, storing the first set of information for subsequent use". However, paragraph 20 on page 3 clearly states that "the invention is the ability to store adjustments made to stimulation levels for estimated electrode thresholds so that the system learns corrections to the estimated equalized levels". Therefore, Mann does disclose the ability to store a first set of information for subsequent use.

Therefore, for the reasons argued above as well as the rejection previously made of record, the examiner considers the pending claims to remain rejected.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-6, 12-13, 17, 20, 22-31, and 33-36 stand rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mann (U.S. Patent Publication 20010034542 A1). Mann disclose on page 2, paragraph 12, "a clinician using such neural stimulation system may immediately jump between two or more electrode sets, each of which has the stimulation magnitude levels automatically adjusted to, e.g., a minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, as different stimulus parameters are tested".

Therefore, since Mann discloses adjusting the stimulation to either the "minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels" and the value of the stimulation level prior to adjustment is zero, then there is necessarily a range.

Furthermore, the Applicant describes on page 14, paragraph 125, "the treatment therapy configuration is within a configuration range of safety. Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient". Therefore, since the stimulation is in a range of a minimum perception threshold level, a

maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, the examiner considers the stimulation to be within a range of safety.

Thus, if the stimulation was delivered to the patient then it would be within a range of safety. If the stimulation would not have been in the range of safety then a corrective action would necessarily be executed.

In the alternative, although the examiner considers Mann to disclose executing a corrective action if a therapy is not safe, Mann discloses the claimed invention except for executing a corrective action if a therapy is not safe. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the treatment to apply a corrective action is the therapy is deemed unsafe in order to provide the predictable results of preventing painful or unnecessary treatment from being administered to a patient.

Mann further teaches a system and method for programming the magnitude of electrical stimuli generated and applied by a spinal cord stimulator (see page 2, paragraph 9). The spinal cord stimulator includes an external programmer that downloads whatever programming data the IPG needs to generate stimulating pulses, such as pulse width, pulse amplitude, and pulse rate (see page 5, paragraph 43). A clinician programs the stimulation ranges by applying stimulation to the patient through different electrode sets and determining the stimulation settings for the sets such as minimum perceived threshold level and maximum perceived threshold level (see page 2, paragraphs 11 and 12). Thereafter, the stimulus applied through the electrode is

adjusted according to the threshold levels (see page 2, paragraph 12). Referring to claims 6 and 27, the electrode sets are named and the thresholds associated with the electrode sets are stored (see page 5, paragraph 48 and page 3, paragraph 20). Regarding claims 2-4 and 35, Mann teaches that the magnitude of the stimulus can only be increased up to the maximum tolerable level perceived by the patient (see page 7, paragraph 56). Further, the patient is able to compare which electrode set produces the best result (see page 7, paragraph 57).

With regards to claims 5 and 36, the current distribution is varied over the electrodes as they are added or subtracted into the electrodes that act as the anodes and cathodes (see page 7, paragraphs 58-71). Referring to claims 12 and 13, the treatment is comprised of an electrode configuration, a stimulation parameter, a therapy level, and a level of tolerability. Additionally, the stimulation parameter is selected from pulse width, pulse amplitude, and pulse rate (see page 5, paragraphs 45, 47-48). Referring to claims 17 and 33, Mann teaches a system and method that determines the tolerable levels of stimulation that will not deliver therapy at a magnitude greater than the maximum tolerable threshold (see claim 16).

Referring to claims 22-24, Mann teaches electrical stimulation to the spinal cord using an implanted system with an external controller as described above. With reference to claims 28-31, Mann teaches multiple electrode sets, each labeled, with associate threshold data for the minimum perceived data and maximum tolerable data (see page 5, paragraphs 47-48). Mann further teaches that a subset of the possible

electrode configurations may be measured and from such measurements estimates may be made of the unmeasured thresholds with accuracy (page 3, paragraphs 17-19).

2. Claims 7-11 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mann or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above. Mann teaches the method and device described above, but does not teach the user labeling the electrode configurations or treating for epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis, anxiety, mood disorder, sleep disorder, or psychiatric disorder. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the neurostimulation system and method as taught by Mann with the label from the user or to treat various nervous system disorders, because Applicant has not disclosed that the label from the user or treating various nervous system disorders provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the label from the device or treating the central nervous system as taught by Mann, because it provides a means by which the user can identify different stimulation settings and it treats any disorder originating in the central nervous system and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Mann. Therefore, it would have been an obvious matter of design choice to modify Mann to obtain the invention as specified in claims 7-11 and 21.

3. Claims 14-16 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mann, or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above, in view of Whitehurst et al (U.S. Patent Publication 20040015205 A1). Mann teaches the system and method described above, but do not teach determining the surface area of the electrodes or the charge density, or using these parameters to determine if therapy should be delivered. Whitehurst et al. teach that the electrodes must have a relatively large surface area in order to maintain safe levels of charge density and current density (see page 3, paragraph 46). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the system and method for neurostimulation taught by Mann with the electrodes with a large surface area to maintain safe levels of charge density.

Regarding claims 15 and 16, Mann in view of Whitehurst et al. discloses the claimed invention except for the calculation of charge density and current. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurostimulation system and method taught by Mann in view of Whitehurst et al, with the calculations for charge density and current since it was known in the art that the equations disclosed by the Applicant are used to calculate current and charge density.

4. Claims 18 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mann, or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above, in view of Esteller et al (U.S. 6594524). Mann teaches the neurostimulation system and method described above, but does not teach drug infusion. Esteller et al.

teach treating neurological disorders by drug infusion that is activated to deliver a minimal amount of drug (see claims 7 and 65). It would be obvious to use drug infusion to treat neurological disorders because certain drugs can correct chemical imbalances in the body. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the neurostimulation system and method taught by Mann with the drug infusion taught by Esteller et al. in order provide the predictable results of correcting a chemical imbalance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
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